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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/737,446	01/10/97	DUPRE J	223/051

HM12/1209

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EXAMINER	
NOLAN, P	
ART UNIT	**PAPER NUMBER**
1644	17

DATE MAILED: 12/09/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/737,446	Dupre
Examiner	**Group Art Unit**
Nolan	1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 10-22-99.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 38-47 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 38-47 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

Part III DETAILED ACTION

1. Claims 38-47 are pending.

2. Claims 38-41 and 43-46 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of GLP 1 (7-36) amide or GLP 1 (7-37) in treating Type I diabetes subcutaneously, does not reasonably provide enablement for the use of any analog to GLP 1 (7-36) amide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to use the invention commensurate in scope with these claims, for reasons supplied in Paper No. 14.

Applicant's arguments filed 10-22-99 have been fully considered but are not found persuasive.

Applicant argues and cites case law which states that every embodiment within a disclosure does not have to be operative in order to be enabling under 35 USC 112, first paragraph, and that experimentation in of itself is not enough to restrict the allowance of broad claims. Applicant further argues that since analogues of GLIP were known at the time of Applicant's disclosure it would require an undue amount of experimentation to practice the full breadth of Applicant's claims.

However, in reviewing the most relevant and recent case law on 35 USC 112 first paragraph, the analysis used in In re Wands, 8 USPQ2D 1400, and Ex parte Forman, et al., 230 USPQ 546, would lead one of skill in the art to believe Applicant is not enabled for the full scope of their claims. In Applicant's specification, there are no working examples of analogues, there is no discussion whatsoever on guidance in how to make an analogue and what one of skill in the art would expect would occur in vivo if said analogue was given to treat diabetes. Furthermore, the Nature of the invention, the GLP-1 peptides have physiological activity by binding to a receptor in vivo and eliciting a physiological effect which helps in the treatment of Diabetes. The State of the Art, Ngo et al., teaches that any changes to a sequence in a peptide (i.e. an analogue) would have unknown effects on its tertiary structure, which one of skill in the art would recognize that tertiary structure and activity, more specifically receptor activity, are inextricably linked. Since the state of the art teaches that mutations to a known peptide have unknown effects and Applicant has no working examples or guidance in their specification as to what an analogue is or as to how it would be made, it would be unpredictable and require an undue amount of experimentation to practice the breadth of Applicant's claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

3. Claims 38-47 stand rejected under 35 U.S.C. § 103 as being unpatentable over Gutniak et al. (V), in view of U.S. Patent 5,424,286,(A), D'Alessio et al., (W), all of record, for reasons supplied in Paper No. 14.

Applicant arguments have been fully considered but are not found persuasive.

Applicant argues that there is no teaching nor suggestion that of use of an agonist that delays gastric emptying.

However, it was art recognized prior Applicant's invention that GLP-1 delays gastric emptying, see page 5, lines 34-36 of Applicant's disclosure, where they cite a prior art article, Wettergren et al., which discloses that GLP-1 is known to cause delay of gastric emptying in humans. So the method taught by the combined references used to reject Applicant's claimed invention under 35 USC 103 would have the expectation of delaying gastric emptying.

Applicant argues that there would be no motivation to user GLP-1 to potentiate insulin release in Type diabetics, since Type I diabetics don't have the ability to produce sufficient insulin and have no secretory response for GLP-1 to amplify.

However, as Applicant has admitted some type I diabetics have decreased insulin release, not absent insulin release, so since there is some release of insulin in Type I diabetics there is some release to amplify.

Applicant argues that the `286 patent teaches away from the Applicant's invention because it misrepresents what the Gutniak article teaches.

The `286 patent clearly teaches the results of the Gutniak et al., article, the `286 patent teaches that "In patients with IDDM (i.e. Type I diabetes), the GLIP (i.e. GLP-1(7-36)amide) treatment

lowered the insulin required by one half.". However, the `286 patent goes on further to teach what one of skill would recognize could be used with the information taught by Gutniak et al., "This glucose dependent activity is a very desirable characteristic for a therapeutic agent that can be used to treat DM avoiding the complications of hypoglycemic side effects" (column 1, in particular).

Applicant argues that the D'Alessio et al., article when considered in its entirety teaches away from Applicant's claimed invention. Applicant argues that D'Alessio et al., points out some of the deficiencies of the Gutniak et al., article by teaching that Gutniak et al., could not determine "whether GLP-1 exerts an effect on insulin sensitivity, or if it promotes insulin dependent glucose utilization. Furthermore because glucose disposal rates were studied only in diabetic subjects, it is not known whether their augmentation by GLP-1 occurs in healthy people and this might compromise a physiologic response of the peptide."

However, as taught by the Title of the article, "Glucagon-like Peptide 1 Enhances Glucose Tolerance Both by Stimulation of Insulin Release and by Increasing Insulin-independent Glucose Disposal". While it is true that the Gutniak et al., article does not teach using GLP-1 for Type I Diabetes treatment, when the results of the Gutniak et al., article are interpreted by those of skill in the art, the `286 patent and further experiments are done to further elucidate the mechanism of action of GLP-1 by D'Alessio et al., it would have been obvious that one of skill in the art would have been motivated with a reasonable expectation of success in arriving at Applicant's claimed invention.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

6. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7401.

Patrick J. Nolan, Ph.D.
December 7, 1999

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SUPERVISORY PATENT EXAMINER
GROUP ~~1800~~ 1640